[3270-F1]

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Information; Identifying Ambiguities, Gaps, Inefficiencies, and Uncertainties in the Coordinated Framework for the Regulation of Biotechnology

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Notice of request for information (RFI).

SUMMARY: The National Biotech and Biomanufacturing Initiative (NBBI) identified biotechnology regulation clarity and efficiency as a priority of the Administration. Thus, the White House Office of Science and Technology Policy (OSTP)—on behalf of the primary agencies that regulate the products of biotechnology, the U.S. Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA)—requests relevant data and information, including case studies, that may assist in identifying any regulatory ambiguities, gaps, inefficiencies, or uncertainties in the Coordinated Framework for the Regulation of Biotechnology, particularly with regard to new and emerging biotechnology products. The information provided will inform regulatory agency efforts to improve the clarity and efficiency of the regulatory processes for biotechnology products.

DATES: Interested persons and organizations are invited to submit comments on or before 5 p.m. ET [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: USDA is managing this docket and is listed as the primary addressee below. All three agencies and OSTP will be considering all submitted comments as part of their efforts to identify regulatory ambiguities, gaps, or uncertainties in the Coordinated Framework.

You may submit information by any of the following methods (Due to time constraints, the eRulemaking Portal is strongly preferred):

- *Federal eRulemaking Portal*: Go to http:// www.regulations.gov. Enter "APHIS-2022-0076" in the Search field. Select the Documents tab, then select the Comment button in the list of documents and follow the instructions to submit your comment.
- *Postal Mail*: Send your comment to the following address. Please include Docket No. APHIS-2022-0076 in the subject line.

  Animal and Plant Health Inspection Service

  US Department of Agriculture

  4700 River Road

  Riverdale, MD 20737

  Attn: Alan Pearson
- *Listening Sessions*: The regulatory agencies and OSTP will host a virtual public listening session on January 12, 2023. If you are interested in registering for the virtual listening session, go to https://www.zoomgov.com/webinar/register/WN_IhbckX4VTiacK0AsyiikKQ. If you are interested in additional listening sessions, please contact Dominique Carter at biotech-regulation@ostp.eop.gov. Summaries of the comments offered during the public listening session and any small listening sessions will be posted to the docket on regulations.gov.

Response to this request for information (RFI) is voluntary. Each individual or institution is requested to submit only one response. Responses should include the name of the person(s) or organization(s) filing the response. Please identify your answers by referring to a specific question number within the response.

Comments submitted in response to this notice are subject to the Freedom of Information Act (FOIA). Responses to this RFI may be posted without change online. No

proprietary information, copyrighted information, or personally identifiable information should be submitted in response to this RFI.

This RFI is issued solely for information and planning purposes and does not constitute a solicitation. There will be no response to individual submissions. Please note that the United States Government will not pay for response preparation, or for the use of any information contained in a response. If submitting a response by mail, please allow sufficient time for mail processing and include the docket number and title.

FOR FURTHER INFORMATION CONTACT:

OSTP: Dominique Carter, biotech-regulation@ostp.eop.gov, tel: 202-456-4444.

EPA: Mike Mendelsohn, Mendelsohn.Mike@epa.gov.

FDA: Eric Flamm, Eric.Flamm@fda.hhs.gov.

USDA: Alan Pearson, alan.pearson@usda.gov.

SUPPLEMENTARY INFORMATION:

Background Information

In 1986, OSTP issued the Coordinated Framework for the Regulation of Biotechnology (51 FR 23302), which outlined a comprehensive Federal regulatory policy for ensuring the safety of biotechnology products. The Coordinated Framework sought to achieve a balance between regulation adequate to ensure the protection of health and the environment while maintaining sufficient regulatory flexibility to avoid impeding innovation.

In 1992, OSTP issued an update to the Coordinated Framework that set forth a risk-based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment (57 FR 6753). The update affirmed that Federal oversight should focus on the characteristics of the product, the environment into which it is being introduced, and the intended use of the product, rather than the process by which the product is created.

In 2015, the Executive Office of the President (EOP) issued a memorandum directing EPA, FDA, and USDA to update the Coordinated Framework. The Federal government subsequently published a National Strategy for Modernizing the Regulatory System for Biotechnology in 2016; and in 2017, OSTP issued another update to the Coordinated Framework. This 2017 update clarifies current agency roles and responsibilities for the regulation of biotechnology products. It provides a table of responsibilities that lists the offices within each agency or agencies that may have regulatory responsibility for a given biotechnology product category, and relevant coordination across the agencies. In addition, it describes memoranda of understanding (MOUs) among the agencies and the types of products and information that are covered within the scope of each MOU. In 2019, E.O. 13874 recognized that advances in biotechnology have the potential to revolutionize agriculture, enhance rural prosperity, and improve the quality of American lives. The E.O. ordered additional steps to be taken to further modernize the regulatory framework.

For details on the current roles and responsibilities of agencies under the Coordinated Framework for the Regulation of Biotechnology, refer to the Unified Website for Biotechnology Regulation *https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home/.*

On September 12, 2022, President Biden issued Executive Order (E.O.) 14081, "Advancing Biomanufacturing and Biotechnology Innovation for a Sustainable, Safe, and Secure Bioeconomy," with the goal of accelerating biotechnology innovation and growing America's bioeconomy across multiple sectors, including health, agriculture, and energy. Among other objectives, E.O. 14081 aims to support the safe use of biotechnology by clarifying and streamlining regulations in service of a science- and risk-based, predictable, efficient, and transparent regulatory system to support the safe use of products of biotechnology. E.O. 14081 directs the EPA, FDA, and USDA to:

- identify any regulatory ambiguities, gaps, or uncertainties in the Coordinated Framework for the Regulation of Biotechnology, through engaging with developers and stakeholders and through horizon scanning for novel biotechnology products;
- provide plain-language information on the regulatory roles, responsibilities, and processes of each agency;
- provide a plan with processes and timelines to implement regulatory reform; and build upon the Unified Website for Biotechnology Regulation.

As noted in the Executive Order, "biotechnology means technology that applies to and/or is enabled by life sciences innovation or product development." Biotechnology products include, for example, organisms (including plants, animals, and microbes) developed through genetic engineering or the targeted or in vitro manipulation of genetic information, some products derived from such organisms, as well as products produced via cell-free synthesis, as determined by existing statutes and regulations.

Questions

Respondents are encouraged to provide relevant data or information, including case studies, regarding regulatory ambiguities, gaps, or uncertainties in the Coordinated Framework, and regarding new and emerging biotechnology products. Respondents need not reply to all questions listed. Please identify your answers as responses to a specific question.

1. Describe any ambiguities, gaps, inefficiencies, or uncertainties regarding statutory authorities and/or agency roles, responsibilities, or processes for different biotechnology product types, particularly for product types within the responsibility of multiple agencies.
    a. Describe the impact, including economic impact, of these ambiguities, gaps, inefficiencies or uncertainties.

2. Provide any relevant data or information, including case studies, that could inform improvement in the clarity or efficiency (including the predictability, transparency, and coordination) of the regulatory system and processes for biotechnology products.
3. Describe any specific topics the agencies should address in plain language on the regulatory roles, responsibilities, and processes of the agencies.
4. Describe any specific issues the agencies should consider in developing a plan to implement regulatory reform, including any updated or new regulations or guidance documents.
5. Describe any new or emerging biotechnology products (e.g., microbial amendments to promote plant growth; food plants expressing non-food substances or allergens from non-plant sources) that, based on lessons learned from past experiences or other information, the agencies should pay particular attention to in their evaluation of ambiguities, gaps, or uncertainties regarding statutory authorities and/or agency roles or processes.
6. Describe any new or emerging categories of biotechnology products on the horizon that the regulatory system and processes for biotechnology products should be preparing to address. Describe any specific recommendations for regulating these new or emerging categories of biotechnology products to guide agency preparations.
7. What is the highest priority issue for the agencies to address in the short term (i.e., within the next year) and in the long term?

Dated: December 15, 2022.

Rachel Wallace,

Deputy General Counsel.

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